Comparing socio-economic benefits and risks of chemicals using socio-economic analysis in the context of REACH

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What is Socio-Economic Analysis ? What are the tools for SEA?

According to the definition given by the European Chemicals Agency[1], socio-economic analysis (SEA) is a method to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where it is not. The analysis typically attempts to include also those effects that are indirect or incompletely reflected by market transactions.

A SEA shall ideally cover all relevant effects related to the introduction of such an action. When the action is to produce, and/or use a chemical, the most important effects to include in the analysis are generally the impacts on health and the environment, on the economy, (e.g. the overall costs to economic actors), and social effects (e.g. on employment and labour quality).

Socio-Economic Analysis is conducted generally using environmental economics tools such as Cost - Benefit analysis (CBA), Cost-Effectiveness Analysis (CEA), or Multi Criteria Analysis (MCA). SEA is also often identified with one or several of these tools.

In Cost Benefit Analysis, costs of benefits of alternative actions are quantified in monetary terms when possible, including items for which the market does not provide a satisfactory measure of economic value (degradation, loss of functionality of ecosystems for instance).

Cost-Effectiveness analysis (CEA) is widely used to determine the least cost means of achieving pre-set targets or goals. CEA can aim at identifying the least-cost option among a set of alternative options that all achieve the targets. In more complicated cases, CEA is used to identify combinations of measures that will achieve the specified target.

Past experience in SEA for designing or enforcing regulations

The use of SEA or one of these tools to support decision-making in environmental issues is of course not new, and we make hereafter a brief review of past experience of SEA in different contexts and in different countries.

[1] http://reach.jrc.it/socio_economic_en.htm

Cost-Benefit Analysis has been quite often used in regulatory analysis of proposed regulations in Canada in the USA, for instance for the ban of lead in gasoline, and more recently in the European Union.
A recent example of the use of Cost-Benefit Analysis in the EU is the Clean Air For Europe Program. In this case, a Cost-Benefit Analysis concluded that the benefits for human heath and the environment of regulating air pollution were significantly higher than the economic cost of new regulation.

Past experience of SEA in chemicals management and main lessons learned

In the field of the regulation of chemicals, the idea that SEA could help finding the "most appropriate" management options for potentially harmful chemicals can be found in many countries regulations, and international organisation documents from long ago :

- In Canada, the Toxic Substances Programs considers CBA for the Life Cycle Management of substances : Socio-economic factors will help determining long-term environmental goals, targets, strategies and time lines to phase out production and use of some substances. Such factors include: the benefits associated with the use or generation of a substance; the cost and feasibility of developing and using alternatives or remediation; the impact on employment, Canadian competitiveness, trade and regional development; and fairness and equity.
- In the US, the Toxic Substances Control Act (TSCA) directs US-EPA to use the least burdensome option to reduce the risk to a level that is reasonable given the benefits provided by the chemical product or process.. However, the number of socio-economic analysis carried out under this Act is quite low.
- In the USEPA "Design for the environment" program, USEPA and industry carry out Cleaner Technologies Substitutes Assessments (CTSA), a methodology for evaluating the comparative risk, performance, cost, and resource conservation of alternatives to chemicals currently used by specific industry sectors. A Social Benefits / Costs assessment is part of the CTSA.
- In Europe, in the framework of the Existing Substances Regulations that is being replaced by REACH, an "Analysis of Advantages and Drawbacks" was recommended for carrying out a Risk Reduction Strategy, in a Commission Technical Guidance Document. The "economic impact" of the alternatives was also to be taken into account when selecting the "most appropriate" risk reduction measures.
- UNITAR, OECD, UNECE (Convention on POPs) and other bodies produced or used guidance on SEA analysis for the Risk Management of Chemicals.

Most, if not all, of these countries or organisations especially consider the Cost-Benefit perspective as the appropriate framework for conducting Socio-Economic Analysis. It seems that there is relatively broad agreement that

1) The CBA theoretical framework of welfare economics is adapted to the aim of chemicals regulations that aim at contributing to sustainable development.
2) The Cost/Benefit approach is preferred because no precise environmental/public health objective is assigned to chemical risk management systems, other than reducing the level of risk to some not quantified "acceptable" threshold. However, Cost Effectiveness Analysis and Multicriteria Analysis are in practice not so much different from Cost Benefit Analysis, when monetary valuation cannot be carried out, and CEA/MCA have over CBA the advantage that efficiency indexes can be chosen with a higher degree of flexibility.

Some of the lessons learnt were that

- There are data availability problems, especially regarding the technical suitability and the cost of substitutes, that limit the extent to which SEA is actually employed and is actually helpful, until now, especially in Europe.
- Going beyond risk analysis towards a quantitative description of the impacts on human health and the environment is very difficult, because dose-response relations and/or exposure data are generally not available
- The overall appraisal of costs and benefits to society in terms of monetary values, even if being the underlying theoretical framework generally accepted, is far from being possible in most of cases
- Absolute comparison of Cost and Benefits is difficult because absolute values of costs and benefits not known, and therefore comparison of relative costs and relative benefits between two scenarios (one scenario of continued use of a substance and one scenario of substituting the substance by another one) are preferred
- Uncertainty and robustness issues are known, but no procedure was available to handle them in practice.

SEAs in the context of REACH

REACH is the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals of the European Union (EU). REACH places greater responsibility on industry to manage the risks that chemicals may pose to health and the environment.

REACH implements an authorisation system aiming to ensure that substances of "very high concern" are adequately controlled, and progressively substituted by safer substances or technologies or only used where there is an overall benefit for society of using the substance. These substances will be prioritised and over time included in Annex XIV. Once they are included, industry will have to submit applications to the Agency on authorisation for continued use of these substances.

In addition, EU authorities (Member States or the European Chemicals Agency) may impose restrictions on the manufacture, use or placing on the market of substances causing an unacceptable risk to human health or the environment.

Figure 1 is a flowchart of the authorisation procedure in REACH in which it is shown that SEA can appear in the following cases :

- **The main case for using SEA** is when the risks posed by the substance cannot be adequately controlled. In this situation, the applicant must assess whether there are alternatives to the substance, and whether the socio-economic benefits of using the substance are higher than the socio-economic impacts (including public health and environmental impacts). The SEA is one of the tools to undertake these mandatory assessments.
  Authorisation may be granted only if there is no alternative and if the benefits of using the substances are higher than the impacts.
- When the risks can be adequately controlled, the SEA is not mandatory but may be used to determine some conditions of the requested authorisation.

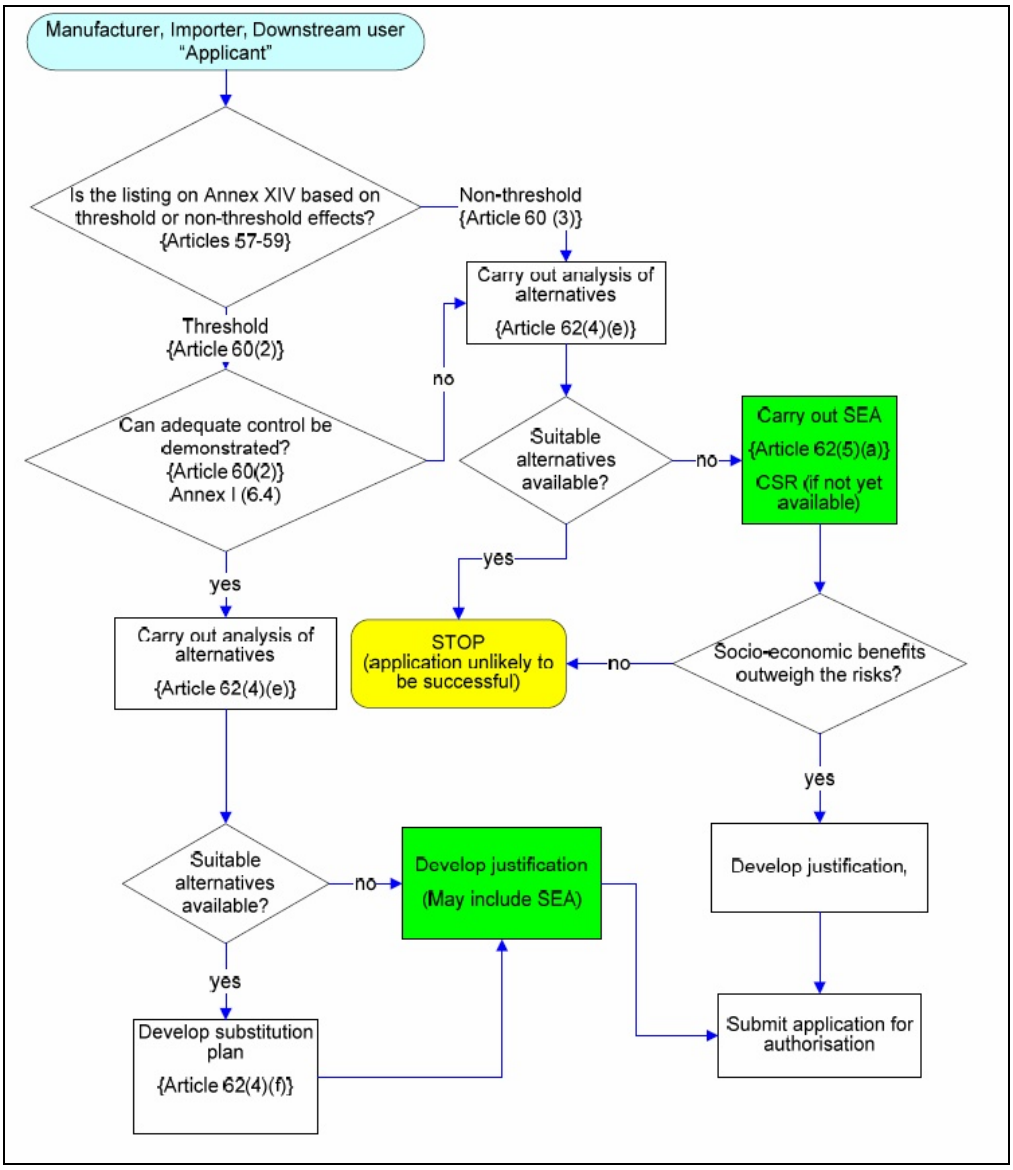

Figure 1 (from Reference [1])

Possible Procedures and Contents of a SEA under the REACH procedure for authorisations

The currently proposed stepwise approach in draft guidance documents for SEA of ECHA is reproduced in Figure 2.
The general idea is to have an iterative approach going through detailed data collection and analysis as far as is really needed to come to a conclusion.
The most important steps, which are also the most difficult to carry out, are

- the description of "what happens" if the authorisation is not granted: how and to what extent the different supply chains down to the final products in which the substance is directly or indirectly involved are affected, and what their likely responses could be.
- When these responses are assessed, the evaluation of the different impacts that these responses imply in terms of socio-economic impacts (impacts on the economy : sectors involved and macro-economic effects) and impacts on human health and the environment.

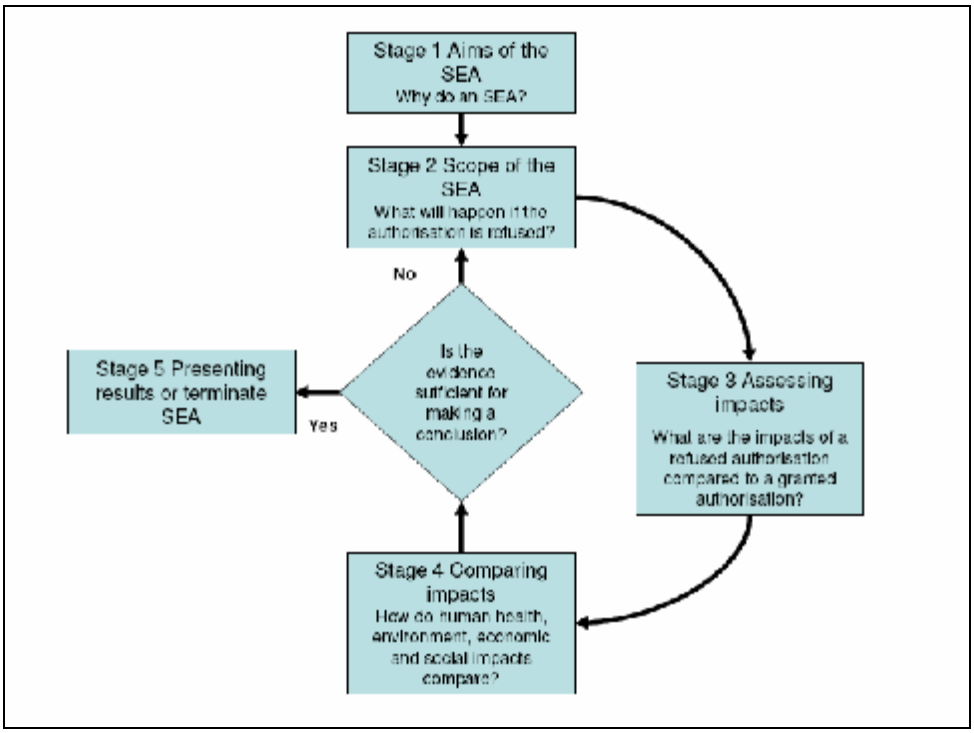

Figure 2 : proposed stepwise approach for conducting an SEA under he REACH autorisation procedure (from [1])

As a result of applying these procedures, the SEA report would typically contain (again according to the draft guidance documents for SEA of ECHA) the following information :

1. SUMMARY OF THE SEA

2. AIMS AND SCOPE OF THE SEA

2.1. Define the objective of the SEA
2.2. Definition of the baseline scenario
2.3. Definition of the “non-use” scenario(s)

3. ANALYSIS OF IMPACTS
3.1. Human Health risks / impacts
3.2. Environmental risks / impacts
3.3. Economic impacts
3.4. Social impacts
3.5. Trade, competition and wider economic impacts

4. COMPARING THE SCENARIOS
4.1. Key assumptions used in the SEA
4.2. Results of uncertainty analysis
4.3. SEA results

5. CONCLUSIONS

APPENDICES:
A.1 LIST OF DATA SOURCES
A.2 DATA COLLECTION APPROACH
A.3 ORGANISATIONS CONSULTED

The evaluation of Socio Economic issues in authorisation applications by the SEA Committee of ECHA

One of the main tasks of the European Chemicals Agency is to give scientific and technical advice to the Commission on authorisation submissions from industry and restriction proposals from Member States.
In order to reach this objective three Committees and a Forum have been established within the Agency before the entry into operation, 1 June 2008.
The Committee for Socio-economic Analysis (SEAC), according to the text of REACH, plays a vital role in formulating the opinion of the Agency in regard to:

- Assessing the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of a substance, when an application for authorisation is submitted. Third party contributions linked to the application will also be assessed (Art. 64(4);
- Evaluating restrictions suggested by a Member State or the European Chemicals Agency and the related socio-economic impacts. Comments and socio-economic analysis submitted by the interested parties will also be assessed (Art. 71).

SEAC has to formulate a draft opinion within 10 months of receipt of application by ECHA, and should give its opinion on socio-economic factors related to the application for authorisation, and the availability and technical and economic feasibility of alternatives

The following Figure 3 shows how the tasks of the SEA Committee are closely linked with the tasks of the Risk Assessment Committee, and how they interact with the other actors in he Authorisation procedure.

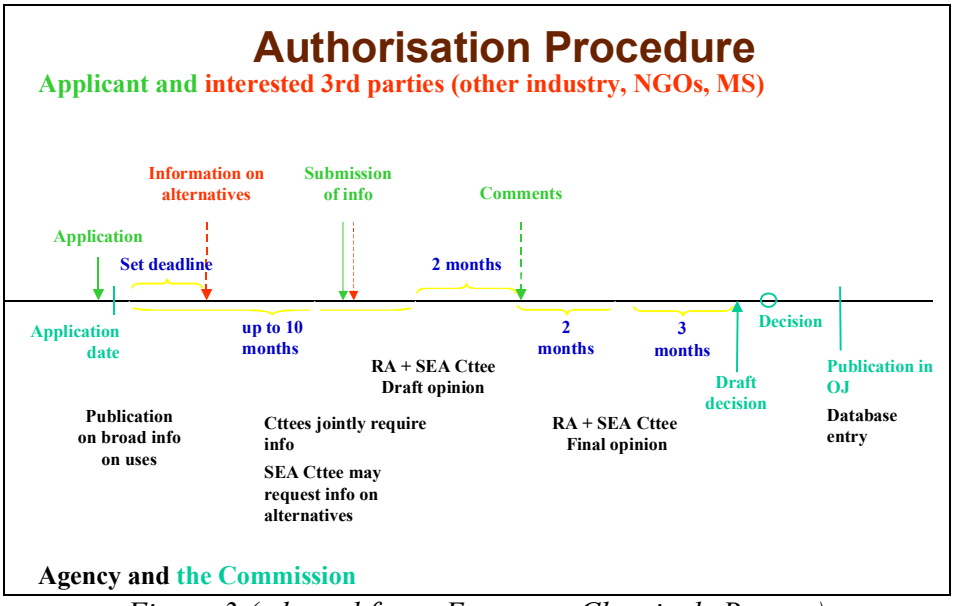

Figure 3 (adapted from European Chemicals Bureau)

Challenges ahead and possible ways forward

The "Stakeholder Expert Group" who participated in the development of the REACH SEA Guidance identified some necessary methodological improvements, especially the need for further development of guidance for assessing health and environmental impacts in an SEA context. As a matter of fact, this first challenge of SEA does not lie in economics, but in the fact that assessing socio-economic impacts first requires that physical impacts themselves are assessed. Assessing "real" physical impacts goes beyond traditional risk assessment, and implies, for instance for human health impacts, to go beyond probabilities and make predictive assessment of the number and severity of cases, making extrapolation from toxic effects to disease.

A second challenge lies in the economic assessment of alternatives, because technical and economic data on the availability of the alternatives may be lacking or difficult to get when carrying out the SEA.
This technical and economic data challenge is classical in environmental regulation, and has been previously, encountered for instance under the Integrated Pollution Prevention and Control Directive (IPPC Directive 96/61/EC), when it came to determine which are the "Best Available Techniques" and write the "BREF documents". To solve this issue, the Commission established a very extensive data collection process in collaboration with industry that takes place under the coordination of the Institute for Prospective and Technological Studies of the Joint Research Center of the EC, at Seville (Spain).
In the case of SEA, the availability of data has very often been one of the main limiting factors in the past. For SEA under REACH, it is desirable that the new process of submission and review of SEAs create, both in Industry and Member States new databases on the cost and effectiveness of options to substitute dangerous chemicals, and new information exchange mechanisms.

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